#### THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today

- (1) was not written for publication in a law journal and
- (2) is not binding precedent of the Board.

Paper No. 19

### UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JEAN-LUC DUBOIS

\_\_\_\_

Application 08/383,912

\_\_\_\_\_

HEARD: FEBRUARY 24, 2000

\_\_\_\_\_

Before PAK, WALTZ and KRATZ, <u>Administrative Patent Judges</u>.

PAK, <u>Administrative Patent Judge</u>.

## DECISION ON APPEAL

This is a decision on an appeal from the examiner's final rejection of claims 4 through 6 and 8 through 11, which are all of the claims remaining in the application.

Appeal No. 1997-0138
Application No. 08/383,912

Claims 4 and 10 are representative of the subject matter on appeal and read as follows:

4. A process for the preparation of a cosmetic or pharmaceutical composition of claim 10 comprising preparing an aqueous emulsion or suspension of a compound of formula

I and at least one lipid compound and optionally additives, stirring the emulsion or suspension at 40E to 80EC and reducing the size of the liposomes.

10. Α cosmetic or pharmace utical composit ion containi (I) ng a dermato gically effecti ve amount

of at least one liposome containing an active compound of the formula

 $\begin{array}{c} \text{wherein} & & R_{\scriptscriptstyle 1} \, \text{is} \\ \text{selected} & & \text{from} \end{array}$ 

the group consisting of -CN,

 $-\mathrm{NO_2}$  and halogen,  $\mathrm{R_2}$  is  $-\mathrm{CF_3}$  or halogen,  $-\mathrm{A-B-}$  is selected from the group consisting of

Appeal No. 1997-0138
Application No. 08/383,912

wherein X and Y are oxygen and  $R_3$  is selected from the group consisting of hydrogen and alkyl of 1 of 4 carbon atoms optionally substituted with -OH or methoxy and wherein the cosmetic or pharmaceutical composition is free of volatile solvents.

Application No. 08/383,912

As evidence of obviousness, the examiner relies on the following prior art:

Evans et al. (Evans) 5,358,752 Oct. 25,
1994 (Filed Feb. 23, 1993)
Gaillard-Kelly et al. (Kelly) 5,411,981 May
2, 1995 (Filed May 18, 1993)

Claims 4 through 6 and 8 through 11 stand rejected under 35 U.S.C. § 103 as unpatentable over the combined disclosures of Kelly and Evans.

We reverse.

The claimed subject matter is directed to a cosmetic or pharmaceutical composition comprising at least one liposome containing a particular dermatologically active compound. The cosmetic or pharmaceutical composition is free of any (not even a trace amount of) volatile solvents since the liposomes employed are prepared without using any such volatile solvents. See specification, pages 11-13.

We find that the examiner has supplied a reasonable basis for employing the liposomes described in Evans as a delivery system for the active dermatological compounds described in Kelly. See Answer, page 3. However, the examiner has

supplied no evidence to demonstrate that the resulting pharmaceutical composition would be free of any volatile solvent<sup>1</sup>. Nor has the examiner supplied any evidence regarding the claimed process for preparing the same.

The examiner argues that the pharmaceutical composition resulting from the combined teachings of Kelly and Evans "would inherently be free of solvent" because "the organic solvent is typically evaporated from the composition in liposome formation." See Answer, pages 4 and 5. However, the examiner has not supplied any factual basis to support the determination that the typical volatile organic solvent evaporation technique would necessarily remove any and all volatile solvents present in the pharmaceutical composition.

See Ex parte Levy, 17 USPQ2d 1461, 1463-64 (Bd. Pat. App. & Int. 1990). It is well settled that inherency cannot be established by probabilities or possibilities. See In re
Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); In re Rijckaert, 9 F.3d 1531, 1534,

28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

<sup>&</sup>lt;sup>1</sup> Evans prepares liposomes in a volatile organic solvent (chloroform). See column 5, example 6.

The examiner also argues that "applicant acknowledges at p. 10 of the disclosure that his process of making the liposomal composition is known in the art and described in other patent literature." See Answer, page 4. Nowhere does the disclosure relied on by the examiner, however, clearly admit that the claimed process was "known . . . and described in other patent literature [at the time of the invention]<sup>2</sup>." See specification, page 10.

In view of the foregoing, we agree with appellant that the examiner has not established a *prima facie* case of obviousness regarding the claimed subject matter.

Accordingly, we reverse the examiner's decision rejecting all of the appealed claims under 35 U.S.C. 103.

## OTHER ISSUE

In the "Response to argument" section of the Answer, the examiner relies on page 10 of the disclosure to show that

<sup>&</sup>lt;sup>2</sup> Moreover, we note that the examiner does not rely on appellant's admission or other patent literature in her statement of rejection. When, as here, the statement of rejection does not include appellant's admission or other patent literature as the prior art supporting the rejection, we need not consider them in evaluating the examiner's rejection. <u>In re Hoch</u>, 428 F.2d 1341, 1342 n. 3, 166 USPQ 406, 407 n. 3 (CCPA 1970).

Application No. 08/383,912

"known in the art and described in other patent literature."
As indicated <u>supra</u>, the reference on page 10 of the specification, as well as other references on pages 2 and 5, have not been included in the statement of the rejection.

Upon return of this application to the jurisdiction of the examiner, the examiner should review these references and consider the patentability of the claimed subject matter in light of this acknowledged prior art. Note that French Patent 2,627,385 and European Patent Applications 342,100 are said to disclose cosmetic and

appellants' process for preparing the liposomal composition is

No time period for taking any subsequent action in connection with this appeal may be extended under  $37 \text{ CFR } \S 1.136(a)$ .

0,580,459 are said to disclose the claimed active compound.

pharmaceutical compositions containing vesicles of liposome

type. Note also that European Patent Applications 494,819 and

#### REVERSED

CHUNG K. PAK )

Appeal No. 1997-0138 Application No. 08/383,912

Administrative Patent Judge	)
	)
	)
	) BOARD OF PATEN
THOMAS A. WALTZ	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
PETER F. KRATZ	)
Administrative Patent Judge	)

CKP:hh

BIERMAN AND MUSERLIAN 600 THIRD AVENUE NEW YORK, NY 10016